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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Publication Date 8-5-03

Certifier 0 00 60

Food and Drug Administration

[Docket No. 2003P-0296]

Romano Cheese for Manufacturing Deviating From Identity Standard;

Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Kerry, Inc., Eau Galle Cheese Factory, and First District Association jointly to market test romano cheese for manufacturing that deviates from the U.S. standard of identity for romano cheese (21 CFR 133.183). The purpose of the temporary permit is to allow the co-applicants to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

DATES: This permit is effective for 15 months, beginning on the date the test product is introduced or caused to be introduced into interstate commerce, but not later than [insert date 90 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Ritu Nalubola, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity issued under section 401 of the

NTP 0296

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued jointly to Kerry, Inc., 352 East Grand Ave., Beloit, WI 53511; Eau Galle Cheese Factory, N6765 State Hwy., Durand, WI 54736; and First District Association, 101 South Swift Ave., Litchfield, MN 55355.

The permit covers limited interstate marketing tests of products identified as "Romano cheese for manufacturing made from cow's milk." These products may deviate from the U.S. standard of identity for romano cheese (21 CFR 133.183) in two ways. First, the product is formulated using an enzyme technology that fully cures the cheese in 2 months rather than 5 months and, second, the product is intended only for further manufacturing into food ingredients. Except for these two deviations, the test product meets all the requirements of the standard. The purpose of the temporary permit is to allow the co-applicants to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

The permit provides for the temporary marketing of a total of 9 million pounds (4.1 million kilograms) of the test product. The test product will be manufactured by Eau Galle Cheese Factory at N6765 State Hwy., Durand, WI 54736 and by First District Association at 101 South Swift Ave., Litchfield, MN 55355. The test product then will be shipped to Kerry, Inc., plants in Wisconsin and Minnesota, where it will be further manufactured into food ingredients. The food ingredients will be distributed by Kerry, Inc., throughout the United States. Each of the ingredients used in the test product must be declared on the labels of the test product as required by the applicable sections of 21 CFR part 101. The permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate

commerce, but not later than [insert date 90 days after date of publication in

the Federal Register].

Dated:

July 17, 2003.

CENTIFIED TO BE A TRUE COPY OF THE ORIGINAL

. Christine Taylor,

Director,

Office of Nutritional Products, Labeling and Dietary

Supplements, Center for Food Safety and Applied Nutrition.

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